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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/735,481	12/12/2003	Claus Garbe	WWELL73.008C1	2551

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EXAMINER

TONGUE, LAKIA J

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 05/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/735,481

Applicant(s)

GARBE ET AL.

Examiner

Lakia J. Tongue

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 February 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2, 6, 31, 33, 35, 37, 41, 43, 47, 48 is/are pending in the application.
- 4a) Of the above claim(s) 6, 31, 33, 35, 41, 47 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2, 37, 43 and 48 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 December 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's response filed on February 17, 2006 is acknowledged. Claims 2, 6, 31, 33, 35, 37, 41, 43, 47 and newly added claim 48 is pending and under consideration. Claims 1, 3-5, 7-30, 32, 34, 36, 38-40, 42 and 44-46 have been canceled and claims 6, 31, 41 and 47 have been withdrawn from consideration.

The text of those sections of Title 35, U.S. Code not included in this action can be found in the prior Office Action.

Objections Withdrawn

1. In view of applicants' response the objection to the specification on page 8, paragraph 9 is withdrawn.
2. In view of applicants' response the objection to claim 1 on page 8, paragraph 10 is withdrawn.

Rejections Maintained

3. The rejection of claims 2, 37, 43 and newly added claim 48 under 35 U.S.C. 102(b) is maintained for the reasons set forth in the previous office action, on page 6, paragraph 8.

The rejection was on the ground that Akerblom et al disclose the protein DCD, which was identified in SEQ ID NO: 1. The expression of DCD in sweat glands was demonstrated using the dot blot method. Akerblom et al

Art Unit: 1645

disclose a polynucleotide and amino acid sequence (SEQ ID NO: 2). SEQ ID NO: 2 is identical to the SEQ ID NO: 1 disclosed in the present application (column 29-30). Moreover Akerblom et al disclose that modifications of the polypeptides include, but are not limited to acetylation, carboxylation, glycosylation, phosphorylation, lipidation and acylation. Post-translational processing which cleaves a "prepro" form of the protein may also be important for correct insertion, folding and/or function (column 11, lines 14-20). Additionally, Akerblom et al disclose that a fusion protein may be engineered to contain a cleavage site located between a HCAP sequence and the heterologous protein sequence (column 8, lines 42-48). Akerblom et al disclose that it can be designed with signal sequences in addition to other recombinant constructions (column 13, lines 14-20). Lastly, Akerblom et al disclose the use of the isolated protein in pharmaceutical compositions. Administration of the composition is accomplished orally or parenterally and can include topical delivery. Pharmaceutical compositions suitable for use in the present invention include compositions where the active ingredients are contained in an effective amount to achieve the intended purpose (column 22, lines 1-6). Inherently, the antimicrobially active peptide secreted from sweat glands is the same as the claimed composition because Akerblom et al disclose an identical peptide and amino acid sequence, which comprises SEQ ID NO: 1 and fragments thereof (SEQ ID NO: 2).

Applicant urges that Akerblom et al do not disclose an isolated antimicrobially active peptide comprising amino acid residues 63-110 (SEQ ID NO: 2) of dermicidin (DCD) protein substantially in isolation from sequences naturally occurring adjacent thereto in the dermicidin protein.

It is the examiners position that claims 2, 37, 43 and newly added claim 48 are drawn to an isolated antimicrobially active peptide comprising amino acid residues 63-110 (SEQ ID NO: 2) of dermicidin (DCD) protein substantially in isolation from sequences naturally occurring adjacent thereto in the dermicidin protein. The examiner is viewing newly added claim 48 as an antimicrobially active peptide comprising a maximum of 50 amino acids of said C-terminal. The term comprising is viewed as open claim language implying that other things may be present; in this case other amino acids can be present. SEQ ID NO: 2 is a peptide that comprises 48 amino acid residues. The examiner is not viewing the claim language to only incorporate the 48 amino acids claimed, but to incorporate the 48 amino acids and others. This is true for claim 48 as well. The examiner is not viewing the claim language to only incorporate a maximum of 50 amino acids of said C-terminal, but to incorporate the 50 amino acids

Art Unit: 1645

and others. Akerblom et al discloses an isolated antimicrobially active peptide comprising amino acid residues 63-110 (SEQ ID NO: 2) (see Figure 2). Moreover, Akerblom et al discloses a fragment (the coding region of the hcap molecule, which encodes a mature protein of 90 amino acids) of the C- terminal (column 2, lines 4-6). The peptide of Akerblom et al appears to be the exact same peptide as the claimed peptide but by a different name. There is nothing on the record via a side-by-side comparison to show that the peptide of the prior art would not have the same activity of the instantly claim peptide. Since amino acid residues 63-110 (SEQ ID NO: 2) are present, the peptide would inherently have antimicrobial activity.

New Grounds of Rejection Necessitated by Amendment

Drawings

4. The drawings are objected to because Figures 2-5 does not accurately indicate what each bar represents. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several

Art Unit: 1645

views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Additionally, the examiner would like to note that applicant has neglected to title the description of the figures in the instant specification. Applicants should amend the specification prior to the description of the figures with "Brief Description of Figures".

Claim Objections

5. Claims 2 and 48 are objected to because of the following informalities:

"dermicidin" is spelled incorrectly as evidenced by UniProtKB/Swiss-Prot entry P81605.

The appropriate spelling is dermicidin. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claim 2 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection. Claim 2 recites "amino acid residues 63-110 (SEQ ID NO: 2) of a derm: cidin (DCD) protein substantially in isolation from sequences naturally occurring adjacent thereto in the dermicidin protein". The instant specification does not contemplate amino acid residues 63-110 (SEQ ID NO: 2) of a dermicidin (DCD) protein substantially in isolation from sequences naturally occurring adjacent thereto in the dermicidin protein. To overcome this rejection applicant must specifically point out the support for this limitation or cancel the new matter from the claims.

Conclusion

7. No claims are allowable.

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Cunningham et al, Identification of a survival-promoting peptide in medium conditioned by oxidatively stressed cell lines of nervous system origin, The journal of neuroscience, 1998; 18(18): 7047-60.

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakia J. Tongue whose telephone number is 571-272-2921. The examiner can normally be reached on Monday-Friday 7-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on 571-272-0864. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1645

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


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